## REMARKS

Applicants gratefully acknowledge the courtesy of a telephonic interview on October 2, 2007. During the interview, Examiner Rawlings and Minh-Quan K. Pham discussed the outstanding rejection under 35 U.S.C. § 112, first paragraph. The Examiner agreed that amending the claims to include the use of PSA together with MIF would obviate the rejection.

The Office Action dated July 25, 2007, has been fully considered. The present Amendment is intended to be a complete response thereto and to place the case in condition for allowance.

Claims 1-93 are pending. Claims 6-10, 16-22, and 24-93 have been withdrawn as being drawn to a non-elected invention. Claim 1 has been amended to include the use of MIF in conjunction with PSA to detect prostate cancer. Support for the amendment is found, inter alia, in the specification of page 4, lines 20-22.

THE CLAIMS ARE ENABLED

Claims 1-5, 11-15, and 23 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner alleges that the claimed process, *per se*, would not necessarily achieve the objective of detecting or diagnosing prostate cancer, "because identical levels of MIF are present in the sera of individuals that are not afflicted with prostate cancer.". *See* Office Action, page 4. Applicant has amended the claim to use MIF in conjunction with prostate specific antigent (PSA) to detect prostate cancer.

Measuring PSA levels has long been the sole serum diagnostic test utilized for assisting clinicians to determine prostate cancer. Researchers and clinicians have long known the limitations of PSA and have been searching for improvements. *See e.g.*, Ford et al., *Cancer*

*Epidemiol. Biomarkers Prev.* 2005, 14(1), 190-194; Wolff et al., *Anticancer Res.* 1997, 17:2993-2994; and Ozen et al., *Am. J. Clin. Oncol.* 2001, 24:610-613. With major advancements, particularly in the past decade in areas of genomics and proteomics, combining serum tests has emerged to improve medical care . Creating a panel test of MIF with PSA creates such an improvement.

MIF is selected to be a panel adjuvant with PSA for several reasons. It is an independent marker from PSA in its expression. The levels of MIF are readily apparent in all individuals allowing it to be examined for over expression with conventional analyzers. Most importantly, it appears to have two advantages that are lacking compared to PSA. First and foremost, higher MIF levels appear to be associated with more aggressive cancers; those that are likely to metastasize to other areas of the body. Second, MIF levels remain lower in benign situations.

MIF, because it is an independent biomarker for prostate cancer distinct from PSA, plays a different role than PSA in the diagnosis and prognosis of prostate cancer. First, MIF serum concentration has higher sensitivity for the detection of prostate cancer, but lower specificity. Therefore, combining the use of MIF and PSA in diagnosing prostate cancer improves both sensitivity and specificity when compared to techniques currently available in the art.

Overall, because PSA alone enables the detection of prostate cancer, the addition of MIF to improve current use of PSA is also enabled. Therefore, the present claims are enabled. Accordingly, Applicant respectfully requests withdrawal of the rejection.

THE CLAIMS SHOULD BE REJOINED

If and when claim 1 is found allowable, Applicant respectfully requests rejoinder of claims 6-10 and 16-22, which have been withdrawn from consideration as being drawn to a non-elected invention. According to MPEP 821.04(a),

> a requirement for restriction should be withdrawn when a generic claim, linking claim, or subcombination claim is allowable and any previously withdrawn claim depends from or otherwise requires all the limitations thereof.

In the present application, claim 1 is a linking claim (*see* Office Action mailed July 12, 2006, page 4); and claims 6-10 and 16-22 depend, directly or indirectly, from claim 1. Thus, in accordance with MPEP 821.04(a), claims 6-10 and 16-22 should be rejoined, if and when claim 1 is found allowable.

CONCLUSION

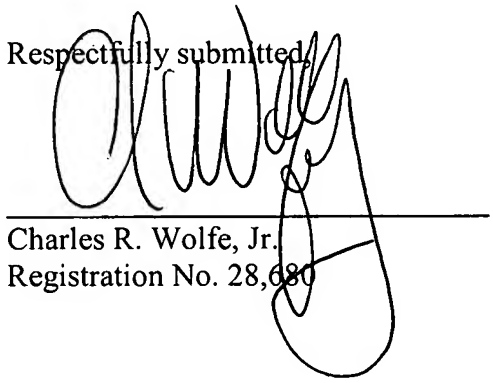
Applicant has responded to the Office Action mailed July 25, 2007. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (111828.0109). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time.

Any fees due are authorized above.

Respectfully submitted,



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